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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,255	12/06/2000	Joel E. Habener	17633/1220	9070

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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	PAPER NUMBER
1647	6

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/731,255	HABENER ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-127* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-127* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 and 36-48, drawn to a method of treating a patient with diabetes mellitus comprising isolating a nestin-positive pancreatic stem cell and transferring the stem cell into the patient, wherein the stem cell differentiates into an insulin-producing cell, classified in class 424, subclass 93.1.

II. Claims 12-24 and 49-66, drawn to a method of treating a patient with diabetes mellitus comprising isolating a nestin-positive pancreatic cell, culturing the stem cell ex vivo, and transferring the progenitor cell into the patient, wherein the progenitor cell differentiates into an insulin-producing beta cell, classified in class 424, subclass 93.1.

III. Claims 25-35 and 67-79, drawn to a method of treating a patient with diabetes mellitus comprising isolating a nestin-positive pancreatic stem, expanding the stem cell to produce a progenitor cell, differentiating the progenitor cell in culture to form pseudo-islet like aggregates, and transferring the pseudo-islet like aggregates into the patient, classified in class 424, subclass 93.1.

IV. Claims 80-84 and 125, drawn to a transplant graft comprising an isolated, nestin-positive human pancreatic stem cell that is not a neural stem cell, classified in class 435, subclass 325.

V. Claims 85, 88-99, 100-101, and 106-117, drawn to a method of treating a patient with liver disease comprising isolating a nestin-positive pancreatic stem cell, and transferring the stem cell into the patient, wherein the stem cell differentiates into a hepatocyte, classified in class 424, subclass 93.1.

VI. Claims 86, 88-99, , 102-103, and 106-117, drawn to a method of treating a patient with liver disease, comprising isolating a nestin-positive pancreatic stem cell, expanding the stem cell ex vivo to produce a progenitor cell, and transferring the progenitor cell into the patient, wherein the progenitor cell differentiates into a hepatocyte, classified in class 424, subclass 93.1.

VII. Claims 87-99, 104-117, drawn to a method of treating a patient with liver disease comprising isolating a nestin-positive pancreatic stem cell, differentiating the stem cell ex vivo to produce a hepatocyte, and transferring the hepatocyte into the patient, classified in class 424, subclass 93.1.

VIII. Claims 118-122 and 126, drawn to a transplant graft comprising an isolated, nestin-positive human liver stem cell that is not a neural cell, classified in class 435, subclass 325.

IX. Claims 123-124 and 127, drawn to a transplant graft comprising an isolated, nestin-positive human stem cell that is not a neural stem cell, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups IV, VIII and IX are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the transplant graft of Group IV comprises an isolated, nestin-positive human pancreatic stem cell. The transplant graft of Group VIII comprises an isolated, nestin-positive human liver stem cell. The transplant graft of Group IX comprises any isolated nestin-positive human stem cell and can be used in materially different methods, such as various diagnostic or therapeutic assays, that the transplant grafts of Groups IV and VIII cannot be utilized in.

b. Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions I-III and V-VII are different methods because they require different ingredients, process steps, and endpoints. Groups I-III and V-VII are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention I requires search and consideration of efficacy of therapy by isolating a nestin-positive pancreatic stem cell and transferring the stem cell into the patient wherein the stem cell differentiates into an insulin-producing cell,

which is not required by the other inventions. Invention II requires search and consideration of efficacy of therapy by isolating a nestin-positive pancreatic cell, culturing the stem cell ex vivo, and transferring the progenitor cell into the patient, wherein the progenitor cell differentiates into an insulin-producing beta cell, which is not required by the other inventions. Invention III requires search and consideration of efficacy of therapy by isolating a nestin-positive pancreatic stem, expanding the stem cell to produce a progenitor cell, differentiating the progenitor cell in culture to form pseudo-islet like aggregates, and transferring the pseudo-islet like aggregates into the patient, which is not required by the other inventions. Invention V requires search and consideration of efficacy of therapy by isolating a nestin-positive pancreatic stem cell, and transferring the stem cell into the patient, wherein the stem cell differentiates into a hepatocyte, which is not required by the other inventions. Invention VI requires search and consideration of efficacy of therapy by isolating a nestin-positive pancreatic stem cell, expanding the stem cell ex vivo to produce a progenitor cell, and transferring the progenitor cell into the patient, wherein the progenitor cell differentiates into a hepatocyte, which is not required by the other inventions. Invention VII requires search and consideration of efficacy of therapy by isolating a nestin-positive pancreatic stem cell, differentiating the stem cell ex vivo to produce a hepatocyte, and transferring the hepatocyte into the patient, which is not required by the other inventions.

c. Inventions IV and I-III/V-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as diagnostic or cell culture assays.

d. Inventions VIII-IX and I-III/V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups VIII-IX and I-III/V-VII are unrelated product and methods, wherein each is not required, one for another. For example, the compositions of Inventions VIII-IX cannot be used together with the claimed methods of Inventions I-IIII/V-VII because these inventions do not recite the use or production of the transplant grafts of Inventions VIII-IX.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BEB
Art Unit 1647
March 21, 2002

Gary L Kunz
GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600